Appl. No.

09/350,043

Filed

July 8, 1999

and the following comments. As a result of the amendments above, Claims 1-16, 19, 21-28, and 30-37 remain pending. Claims 38-53 have been added.

The specific changes to the amended claims are shown on a separate set of pages attached hereto and entitled <u>VERSION WITH MARKINGS TO SHOW CHANGES MADE</u>, which follows the signature page of this Amendment. On this set of pages, the insertions are <u>double underlined</u> and the deletions are <u>struckthrough</u>.

Rejections Under 35 U.S.C. § 112, ¶ 1

The Examiner has rejected Claims 1-16, 19, 21-28 and 30-37 under 35 U.S.C. § 112, ¶ 1, because, in the Examiner's view, the specification does not enable the use of any ethoxylated oil with an alcohol as a transdermal enhancer. The Examiner has indicated, however, that the specification does enable ethoxylated castor oil, jojoba oil, corn oil, and emu oil. The Examiner states "It is clear from the specification (page 19) that specific types and molar amounts of oils may be ethoxylated via ethylene oxide" (See Office Action page 2). The Examiner notes that the claims will be allowed if the § 112, ¶ 1, rejection is overcome.

In an effort to expedite allowance of the case, Applicant has amended the claims to recite the specific ethoxylated lipids mentioned in the specification. Applicant reserves the right, however, to pursue broader claims in a continuing application. Applicant submits that the claims are now in condition for allowance and such action is earnestly solicited.

CONCLUSION

Claims 1-16, 19, 21-28, and 30-37 are pending in the application and Claims 1, 2, 12, 19 and 30 have been amended to conform with the Examiner's suggestion for overcoming the enablement rejection under 35 U.S.C. § 112, ¶ 1. Support for this Amendment can be found in the specification, specifically pages 19.

The undersigned has made a good-faith effort to respond to all the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Eric S. Furman, at (619) 687-8643 (direct line), to resolve such issue promptly.

Appl. No. Filed

09/350,043

:

July 8, 1999

No fees are seen as being necessary for the filing of this response, however, the Commissioner is authorized to charge any fees in connection with this paper to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/11/2m2

By:

Eric S. Furman, Rh.D. Registration No. 45,664 Attorney of Record 620 Newport Center Drive Sixteenth Floor Newport Beach, CA 92660 (619) 235-8550

S:\DOCS\ESF\ESF-4612.DOC:sad2 011102

Appl. No. Filed

09/350,043

July 8, 1999

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

(2X AMENDED) A transdermal delivery system comprising:
 an ethoxylated lipid selected from the group consisting of castor oil, jojoba oil,
 corn oil, and emu oil;

an alcohol mixed with the ethoxylated lipid so as to form a penetration enhancer; an aqueous adjuvant mixed with the penetration enhancer, wherein the aqueous adjuvant comprises *Aloe Vera*; and

a delivery agent mixed with the aqueous adjuvant and the penetration enhancer.

- 2. (2X AMENDED) The transdermal delivery system of Claim 1, wherein the ethoxylated lipid is a vegetable or animal oil havinghas at least 20 ethoxylations per molecule.
 - 12. (2X AMENDED) A transdermal delivery system comprising:
 an ethoxylated oil selected from the group consisting of castor oil, jojoba oil, corn
 oil, and emu oil;

an alcohol mixed with the ethoxylated oil so as to form a penetration enhancer; Aloe Vera mixed with the penetration enhancer; and

- a therapeutically effective amount of capsaicin or NSAID or both mixed with the penetration enhancer and *Aloe Vera*.
- 19. (2X AMENDED) A transdermal delivery system comprising:
 an ethoxylated oil selected from the group consisting of castor oil, jojoba oil, corn
 oil, and emu oil;

an alcohol mixed with the ethoxylated oil so as to form a penetration enhancer; an aqueous adjuvant mixed with the penetration enhancer, wherein the aqueous adjuvant comprises *Aloe Vera*; and

- a therapeutically effective amount of a delivery agent having a molecular weight of more than 2,000 daltons mixed with the penetration enhancer and aqueous adjuvant.
- 30. (2X AMENDED) A method of making a transdermal delivery system comprising: providing an ethoxylated oil selected from the group consisting of castor oil, ioioba oil, corn oil, and emu oil;

Appl. No.

09/350,043

Filed

July 8, 1999

mixing the ethoxylated oil with an alcohol, nonionic solubilizer, or emulsifier so as to form a penetration enhancer;

mixing the penetration enhancer with an aqueous adjuvant, wherein the aqueous adjuvant comprises *Aloe Vera*; and

mixing the penetration enhancer and aqueous adjuvant with a delivery agent and thereby making the transdermal delivery system.

S:\DOCS\ESF\ESF-4612.DOC:sad2 011102